DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9/6462

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

April 12, 2004

Ref: 2004-DAL-WL-14

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. George N. Abdou, President
Texas Orthopaedic Products & Services, LLC
805 Riding Club Road
Rockwall, Texas 75087

Dear Mr. Abdou:

We are writing to you because on November 13-14, 2003, an investigator from the Food and Drug Administration (FDA) conducted an inspection of your Rockwall, Texas, facility that revealed serious regulatory problems involving your patient protective restraints, your electrodes for a powered muscle stimulator, and a powered muscle stimulator you distribute. These products are manufactured and/or distributed by your firm.

Under the Federal Food, Drug and Cosmetic Act (the Act), these products are medical devices as defined by Section 201(h) of the Act, because they are used to diagnose or treat medical conditions. The Act requires that manufacturers of medical devices obtain marketing clearance for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that newly introduced medical devices are safe and effective or substantially equivalent to other devices already legally marketed in this country.

The inspection revealed that your devices are not manufactured in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. These violations cause your devices to be adulterated within the meaning of section 501(h) of the Act. Significant deviations include, but are not limited to, the following:

1. Failure of management with executive responsibility to ensure that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization, as required by 21 CFR 820.20. For example, your firm has not established (a) procedures for management review, internal audit, and complaint handling; and (b) procedures for device assembly and repackaging, acceptance or rejection of finished devices, control of nonconforming products, and device history records; and (c) design

control procedures and design history records for your patient protective restraints (FDA-483, Item #1).

2. Failure to maintain complaint files and failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). For example, your firm (a) has not established written complaint handling procedures to indicate how complaints are received, investigated, and documented; and (b) has not documented customer complaints (FDA-483, Item # 7).

3. Failure to establish and maintain procedures to control the design of the devices to ensure that specified design requirements are met, as required by 21 CFR 820.30. For example, your firm has not established procedures and documentation to include design plans, design inputs, design outputs, design reviews, design verification and validation, design risk analysis, design transfer, design changes, and design history files for your patient protective restraints (FDA-483, Item #2).

4. Failure to establish and maintain procedures for acceptance of incoming product, as required by 21 CFR 820.80(b). For example, your firm has no written procedures for inspecting, testing, or verifying (a) incoming components used in the assembly of your patient protective restraints and bulk powered muscle stimulators and electrodes. In addition, the results of your acceptance or rejection were not documented (FDA-483, Item #4).

5. Failure to establish and maintain process control procedures to include documented instructions, standard operating procedures (SOPs), and methods that define and control the manner of production, as required by 21 CFR 820.70(a)(1). For example, your firm has not established (a) written procedures for assembling and testing or inspecting your patient protective restraints; and (b) written procedures for repackaging powered muscle stimulators and electrodes (FDA-483, Item #5).

6. Failure to establish and maintain procedures to control product that does not conform to specified requirements, including the identification, documentation, segregation, disposition, and investigation of nonconforming products, as required by 21 CFR 820.90(a). For example, your firm has not established written procedures for handling nonconforming products and kept records of your evaluation and disposition of nonconforming products (FDA-483, Item #6).

7. Failure to establish and maintain procedures to ensure that device history records for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record, as required by in 21 CFR 820.184. For example, your firm has no device history records in order to document device assembly acceptance results, device labeling and serial numbers, and dates of manufacture for your patient protective restraints and repackaged powered muscle stimulators and electrodes (FDA-483, Item #10).

Because you do not have marketing clearance from the FDA, marketing your patient restraints and your repackaged electrodes, is in violation of the law. In legal terms, the products are adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. The patient restraints and your repacked electrodes are misbranded under the Act because you did not submit section 510(k) premarket notifications which show that your devices are substantially equivalent to other devices that are legally marketed. Until you submit section 510(k) premarket notifications and FDA reviews them and notifies you that you may market your devices, your products are also adulterated under the Act because the law requires, and you do not have, approved premarket approval applications that show your devices are safe and effective.

Your patient protective restraints and repackaged electrodes are also misbranded within the meaning of section 502(f)(1) because they fail to provide adequate directions for use. You can find guidance on how to prepare adequate directions for use for the patient restraints in the guidance document entitled "Guidance on the Content of Premarket Notification [510(k)] Submissions for Protective Restraints".

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Additionally, no premarket submissions for Class III devices to which QS regulation deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected. Also, Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

Additionally, you should be aware that the labels your firm stick on the individually packaged powered muscle stimulators misbrand these devices because they do not state "Distributed by:" and create the impression that your firm manufactures these devices.

Please let this office know what steps you have taken to correct these problems within fifteen (15) working days from the date you received this letter. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your corrections. Please direct your response to Mr. Thao Ta, Compliance Officer, Food and Drug Administration, Dallas District Office, 4040 N. Central Expressway, Suite 300, Dallas, Texas 75204.

Finally you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers, International and Consumer Assistance at 1-800-638-2041 or through the Internet at http://www.fda.gov.

Sincerely,

Michael A. Chappell
Dallas District Director

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